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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,617

04/25/2005

Wenlong Deng

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1639

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07/31/2006

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/510,617

Applicant(s)

DENG, WENLONG

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/7/04, 4/25/05, 5/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the claims filed on 07 October 2004.

Claims 1-10 are currently pending.

Claims 1-10 are currently under examination.

Specification

The abstract of the disclosure is objected to because it appears to be a literal translation into English from a foreign language. The abstract is poorly written and should be corrected to convey what exactly Applicant's invention is. The entire abstract needs to be rewritten. Correction is required. See MPEP § 608.01(b).

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The disclosure is objected to because of the following informalities:

The entire specification is replete with indefinite and functional or operational language, failing to conform with current U.S. practice. The specification appears to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors and should be edited and corrected to include the proper tenses, phraseology, articles and many sentences should either be omitted or heavily corrected. One example of such a sentence under the heading "The background of the invention", line 3. The sentence reads, "The medicine research for

curing RA has continued about a century” and is poorly written and unclear. This whole sentence needs to be corrected or omitted and there are many others throughout the specification with similar grammatical and idiomatic errors. Furthermore, there are several abbreviations, such as TNF α ntagon, IL-1 inhibitor and PAF inhibitor (See page 1, “The Background of the Invention” line 17 and TCM (See page 2, line 1) that are not defined. Pages 3-6 contain the term weightinweight, which makes no sense. Appropriate correction of the entire specification is required.

Claim Objections

Claims 1-10 are objected to because of the following informalities: Claim 2 should read “The pharmaceutical composition according to claim 1 ~~made from the following materials~~ comprising: *Tripterygium hypoglaucum* (Levl.) Hutch 1-4 parts by weight, *Epimedium brevicornum* Maxim. 1-4 parts by weight, *Lycium barbarum* L. 1-4 parts by weight and *Cuscuta chinensis* Lam. or *Cuscuta australius* R. Br. each 1-4 parts by weight” and Claim 3 should read “The pharmaceutical composition according to claim 1 ~~made from the following materials~~ comprising: *Tripterygium hypoglaucum* (Levl.) Hutch 2 parts by weight, *Epimedium brevicornum* Maxim. 2 parts by weight, *Lycium barbarum* L. 1 part by weight and *Cuscuta chinensis* Lam. or *Cuscuta australius* R. Br. 1 part by weight”. Similar corrections should be made to Claims 1 and 4. Appropriate correction is required.

Claims 1-10 are objected to because of the following informalities: Names of all of the herbs should be italicized. Appropriate correction is required.

Claim 4 is objected to because of the following informalities: icariine, deuteron-icariine I, deuteron-icariine II and glyc-icariine A are incorrectly spelled and written. The correct spelling for "icariine" in all instances is icariin. Appropriate correction is required.

Claim 7 is objected to because of the following informalities: Claim 7 contains the abbreviations, WLD and D101, in line 13. Neither abbreviation is defined in the claims nor is either defined in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 provide for the use of a pharmaceutical composition in the manufacture of a medicament for treating the rheumatoid and rheumatoid arthritis, the use of a pharmaceutical composition in the manufacture of a medicament for treating the systemic lupus erythematosus and the use of a pharmaceutical composition in the manufacture of a medicament for treating the chronic nephritis, Crohn's disease and lepra reaction and the other autoimmune disease, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 8-10 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1-3 are rendered uncertain by the phrase "A pharmaceutical composition for treating rheumatism characterized in that, it is made from the following materials: *Tripterygium hypoglaucum* (Levl.) Hutch: *Epimedium brevicornum* Maxim. *Lycium barbarum* L. *Cuscuta chinensis* Lam., *Cuscuta australis* R. Br. Wherein the materials must be composed of *Tripterygium hypoglaucum* (Levl.) Hutch and one or two or three other herbs in the rest 3 herbs" in Claim 1, "The pharmaceutical composition according to claim 1 made from the following materials: *Tripterygium hypoglaucum* (Levl.) Hutch 1-4 part by weight, *Epimedium brevicornum* Maxim. 1-4 part by weight, *Lycium barbarum* L. 1-4 part by weight, *Cuscuta chinensis*

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Lam., *Cuscuta australis* R. Br. 1-4 part by weight" in claim 2 and "The pharmaceutical composition according to claim 1 made from the following materials: *Tripterygium hypoglaucum* (Levl.) Hutch 2 part by weight, *Epimedium brevicornum* Maxim. 2 part by weight, *Lycium barbarum* L. 1 part by weight, *Cuscuta chinensis* Lam., *Cuscuta australis* R. Br. 1 part by weight" in claim 3. Claim 1 is rejected because it is unclear as to whether both *Cuscuta chinensis* Lam. and *Cuscuta australis* R. Br. are being used or if just one is being used at a time, furthermore, the claim is written so poorly, it is unclear as to what Applicant is actually claiming. It appears that Applicant is saying the composition comprises one or more of the following herbs: *Tripterygium hypoglaucum* (Levl.) Hutch: *Epimedium brevicornum* Maxim. *Lycium barbarum* L. **and** *Cuscuta chinensis* Lam. **or** *Cuscuta australis* R. Br. If this is the case, then the claim should be corrected to recite this. Claims 2 and 3 are rejected because the amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" amount of the total composition. It is also unclear as to whether Applicant is using both *Cuscuta chinensis* Lam. and *Cuscuta australis* R. Br. or just one in Claims 2 and 3. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 4 are rendered uncertain by the phrase "The pharmaceutical composition according to claim 1, characterized in that, it can be made from the correspond effective constituents of the materials above-mentioned as following that *Epimedium brevicornum* Maxim. can be replaced by one or more than one among icariine, deuteron-icariine I, deuteron-icariine II and glyc-icariine A, *Tripterygium*

hypoglaucum (Levl.) Hutch can be replaced by diterpenoids, triterpinoids and alkaloids compound thereof and *Lycium barbarum* L. can be replaced by flavone contained thereof" because "the correspond effective consitutents of the materials above-mentioned" is unclear as is the entire rest of the claim. It appears that Applicant is claiming that the pharmaceutical composition of claim 1 may be made by substituting one or more of the following: icariine, deuteron-icariine I, deuteron-icariine II and glyc-icariine A for *Epimedium brevicornum* Maxim. and that diterpenoids, triterpinoids and alkaloid compounds may be substitutes for *Tripterygium hypoglaucum* (Levl.) Hutch and that flavones may replace *Lycium barbarum* L., however, it is unclear as to whether these substitutions can occur together (i.e. all three of these herbs may be replaced in one composition with one or more of the alternative compounds) or if these substitutions are made one at a time (one herb is substituted with one or more of the alternative compounds. Furthermore, it appears that there is not such compound as deuteron-icariine I, deuteron-icariine II or glyc-icariine (which appears to be an abbreviation of some sort). Is Applicant claiming deuterated icariine? What is glyc-icariine? The specification does not help and does not define these terms, either, so it is impossible to know what Applicant is claiming. The only compound found was icariine (which is incorrectly spelled, See Claim Objections above) which is inherent to *Epimedium brevicornum* Maxim. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 5 are rendered uncertain by the phrase "A method of preparing the pharmaceutical composition according to claim 1, 2 or 3,

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characterized in that, it includes the processes under-mentioned: The raw herbs are weight; and the *Epimedium brevicornum* Maxim. and *Tripterygium hypoglaucum* (Levl.) Hutch. were cut into pieces respectively; including raw material or crushed powder of *Lycium barbarum* L. and *Cuscuta chinensis* Lam. four herbs hereinbefore, were extracted with 0-95% ethanol at 10-98 °C respectively or combinatively for continuing 1-4 times. Ethanol was recycled respectively or combinatively in extracted fluid, then extraction was concentrated, dried, crushed, mixed uniformly or proportionally, manufactured to dosage form adopted in clinical work; Raw herbs were weighed: *Epimedium brevicornum* Maxim. and *Tripterygium hypoglaucum* (Levl.) Hutch. were cut into pieces, boiled out in water for three times respectively, and *Lycium barbarum* L. or *Cuscuta chinensis* Lam. were immersed in water of 80 °C – 95 °C for 1-3 times respectively. Decoction or immersion fluids of three times of each herb were blended respectively, then mixture fluid was respectively poured through corresponding macropore polymeric adsorbant column. After absorption, resin column was washed with water until effluent became clear, then was eluted with 30-99.5% ethanol until color of eluent became from deep to very weak while ethanol liquid was forced out from the column with water. Eluent was mixed with the ethanol liquid. The weight of total eluent was 1-8 fold of the herbs; eluent of each herbs was recycled, concentrated to specific gravity of 1.10 respectively, then extractive of every herbs were obtained by respective or combinative spray drying, which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work". This claim is confusing, poorly written and completely vague. First of all, it appears that this claim contains two

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different methods of making the instantly claimed invention. If this is the case, the claim should be corrected to reflect this or else the methods should be separated into two different claims. Secondly, it is impossible to even determine what the method steps are since there is no indication of when one step ends and another step begins nor is there any organization within the claim to direct one of ordinary skill in the art how to make this invention nor is the method clearly stated. Finally, there are several spelling and grammatical errors, as well as incorrect terms and overuse of the word "respectively". The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 6 are rendered uncertain by the phrase "A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it can be made into any dose forms adopted in the clinical work such as hard gelatin capsule, soft gelatin capsule, tablet, granule and injection". The term "clinical work" is unclear and makes no sense. It appears that Applicant is attempting to describe what form the pharmaceutical composition is in. The claim should be rewritten to reflect this. Upon rewriting the claim, make sure that the article is correct. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 7 are rendered uncertain by the phrase "A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned: *Tripterygium hypoglaucum* (Levl.) Hutch. were cut into pieces, extracted three times after 13, 10 10-

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fold added in repectively, each time lasting 1 hour, *Epimedium brevicornum* Maxim. was cut into segments, extracting three times after 15, 10, 10-fold water was added in respectively, each extraction lasting 1 hour; *Lycium barbarum* L. was crushed to raw powder, immersed in 20-fold water of 80-95°C for 1 hour, *Cuscuta chinensis* Lam. was crushed to raw powder, immersed in 31-fold water of 90 °C for 1 hour, decoction or immersion fluids of four herbs were filtered respectively, poured through WLD or D101 or other type of macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, eluent was commenced to collect; when the color of effluent became very weak, elution was over. Eluent of each herbs was recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained, which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work" as claim 7. It is difficult to tell what the method steps are since there is no indication of when one step ends and another step begins nor is there any organization within the claim to direct one of ordinary skill in the art how to make this invention nor is the method clearly stated. Also, there are several spelling and grammatical errors, as well as incorrect terms throughout the claim. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 8 and 10 are rendered uncertain by the phrase "the rheumatoid" in Claim 8, line 2 and "the chronic nephritis, crohn's disease and lepra reaction and the other autoimmune disease" in Claim 10, lines 2 and 3. What is "the rheumatoid"? "The rheumatoid" does not exist and is completely undefined both within

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the claim and within the specification. Crohn's disease (which should be capitalized) is completely unrelated to lepra reaction and should not be written in the claim in such a way as to make it appear that these terms are linked. What is "the other immune disease"? There are numerous immune diseases and there is no indication as to what immune disease Applicant is referring to. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claims 8-10 recite the limitation "the rheumatoid" in Claim 8, line 2, "the systemic lupus erythematosus" in Claim 9, lines 2 and 3 and "the chronic nephritis" and "the other autoimmune disease" in Claim 10, lines 2 and 3. There is insufficient antecedent basis for these limitation in the claims.

The claims are narrative in form and replete with indefinite and functional or operational language, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The claims must be clearly and positively written. The claims must be organized and correlated in such a manner as to present a complete understanding of the instantly claimed invention. The claims must be in one sentence form only.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 8-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Guo et al. (N*, CN 1178697, Reference Submitted by Applicant. The translation submitted by Applicant gives Xu Ruixin as the Applicant of CN 1178697, however, the European Patent Office Website provides two names on this invention).

Guo teaches a medicine for treating rheumatism comprising Tripterygium hypoglaucom Hutch and wolfberry (wolfberry is the common name of *Lycium barbarum* L.).

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (N*, CN 1178697, Reference Submitted by Applicant. The translation submitted by Applicant gives Xu Ruixin as the Applicant of CN 1178697, however, the European Patent Office Website provides two names on this invention).

The teachings of Ruxin are set forth above and applied as before.

The teachings of Ruxin are set forth above. Ruxin does not expressly teach a pharmaceutical composition for treating rheumatism comprising *Tripterygium hypoglaucum* in an amount of 1-4 parts by weight and *Lycium barbarum* in an amount of 1-4 parts by weight or a pharmaceutical composition for treating rheumatism comprising *Tripterygium hypoglaucum* in an amount of 2 parts by weight and *Lycium barbarum* in an amount of 1 part by weight. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the amounts of *Tripterygium hypoglaucum* and *Lycium barbarum* in a pharmaceutical composition for treating rheumatism because at the time the invention was made, it was known in the art that

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Tripterygium hypoglaucum and *Lycium barbarum* could be used together in a medicine to treat arthritis, as clearly taught by Ruxin.

Therefore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose an amount of *Tripterygium hypoglaucum* and *Lycium barbarum* thereof to provide a preparation comprising *Tripterygium hypoglaucum* and *Lycium barbarum* to treat rheumatism because at the time the invention was made, a medicine for treating rheumatism comprising *Tripterygium hypoglaucum* and *Lycium barbarum* was known, as clearly taught by Ruxin. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of solvent used to perform an extraction and determining an appropriate type of solvent to use in an extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

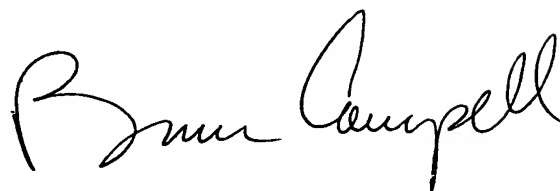
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
July 21, 2006

A handwritten signature in black ink, appearing to read "Bruce R. Campell", written in a cursive style.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600